REMARKS

Claim Rejections - 35 U.S.C. §103

The Examiner rejected claims 1, 3, 4, and 9-13 as allegedly being unpatentable over United States Patent No. 4,838,258 to Dryden in view of United States Patent No. 4,517,404 to Hughes and United States Patent No. 5,526,849 to Gray.

The Examiner contends that "The patent to Dryden discloses the recited limb for a breathing circuit comprising a very thin walled conduit as seen in figure 4 . . ." Applicant submits that this is simply not the case because the conduit of Dryden is not less than 50 microns thick as claimed in claim 1.

Similarly, the combination of Dryden with Hughes does not result in a limb for a breathing circuit having a wall thickness less than 50 microns as required by claim1.

With respect to the combination of Dryden and Gray, the Examiner alleges that:

> It would have been obvious to one skilled in the art to modify the tube in Dryden to have walls of any thickness desired including less than 50 microns as suggested by Gray where such sets forth known equivalent thicknesses of hoses of the same structure and for the same type of use, and where such would provide for a lighter hose if thickness were restricted.

However, the Examiner has not suggested any common sense motivation or realistic motivation as to why a person of ordinary skill in the art would take the hose of Dryden and reduce the wall thickness (allegedly according to Gray), to a point where the tube would contract along the length of the conduit (due to fluctuating internal pressure) and become unsuitable for its intended purpose. Applicant submits that the person of ordinary skill in the art at the priority date of the present application, would recognize that while a lighter conduit might improve patient comfort, such a thin conduit (i.e. less than 50 microns) would be unsuitable for use as a breathing limb due

to the fluctuating volume. This effect is identified in the description of the present application. Due to inherent weight and flexibility penalty, the designer of the existing hose of Dryden is extremely unlikely to have made the wall thickness any greater than that minimally necessary to provide the required strength against buckling, kinking, and axial contraction/expansion. Applicant submits that it was not obvious to continue to reduce the wall thickness indefinitely, and especially not to less that 50 microns.

Further, Gray relates to air conditioning ducts which do not operate under the same conditions as a breathing circuit limb. Claim 1 requires a "breathing gases passageway" and a person of ordinary skill in the art would immediately recognize that the "fluctuating internal pressure" of claim 1 was due to the patient's varying breath-to-breath air flow. The genus of the claims and the summary of the prior art make the meaning of the claim language quite clear in this respect.

An air conditioning duct does not experience such rapid cyclic internal pressure fluctuations, but a rather more 'steady state' condition for the majority of time. While Applicant defers to the Examiner's own experience that some volume changes occur in such ducts when the demand changes, Applicant submits that these must not be considered particularly important, because such ducts are **not** reinforced against these volume changes. Presumably, this is because the duct is hidden in a roof cavity and typical air conditioning control systems are not sensitive to the ducts occasional volume changes. In contrast, the close proximity of a breathing conduit to the patient and the nature of automated ventilating control makes the continual contraction and expansion of a breathing conduit every few seconds unacceptable.

If the field of air conditioning ductus reaches *any* sort or reinforcement against this effect, it is *external* to the duct, i.e. attach the ends to a rigid structure, and/or perhaps attach the duct at several discrete points along its length to a rigid structure.

Since Gray does not actually disclose or teach a method of reinforcing, and the loosely coiled inner hose of Dryden is not "an elongate reinforcing member lying freely within said very thin walled conduit along a non-tortuous path", the cited combination does not contain all of the claimed limitations specified in claim 1. Therefore, Applicant submits that the claims are allowable.

With regard to claim 3, Applicant notes that none of the cited prior art discloses blind termination of the inner tube. Each prior art reference discloses conveying something all the way through the inner tube and exiting (or entering) at the respective ends. It would not be obvious to a person of ordinary skill in the relevant art to blind terminate any of the tubes of the cited prior art because they could not perform their function, unless the tubes remain open ended. Thus, claim 3 is allowable.

Claims 1, 2, 5, 7, 8, 14-16 and 19 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over United States Patent No. 3,163,707 to Darling in view of Gray.

The Examiner alleges that "The patent to Darling discloses the recited limb for a breathing circuit comprising a very thin walled conduit as seen in figure 1 . . ." Applicant reiterate that this is simply not the case because the conduit of Darling is not less than 50 microns thick as claimed in claim 1. As noted above, the reduction of wall thickness of th conduit is **not** merely a choice of mechanical expedients used in routine experimentation to find optimum values. Conventional teaching in the relevant art was that there is a minimum wall thickness

(significantly grater than 50 microns), below which breathing circuit conduits are not fit for their purpose due to fluctuating volume changes.

With respect to the combination of Darling And Gray, the Examiner alleges that:

> It would have been obvious to one skilled in the art to modify the tube in Darling to have walls of any thickness desired including less than 50 microns as suggested by Gray where such sets forth known equivalent thicknesses of hoses of the same structure and for the same type of use, and where such would provide for a lighter hose if thickness were restricted.

Applicant reiterates all of their submissions above in relation to the combination of Dryden and Gray, i.e., that there is not motivation to reduce the wall thickness to a point where the conduit is unsuitable for its purpose.

Further, Applicant emphasizes the fact that the intended use for the hose of Darling is for fighter aircraft where "severe conditions of stress and strain" cause axial elongation when the pilot ejects. It is certain that a wall thickness of "less than 50 microns" as claimed would be wholly inappropriate. The passage in Column 1, line 24-26, suggests that the designer was conscious of the trade off and was limited by "minimum requirements relative to flexibility and non-kinking characteristics and cross-sectional resistance to crush." Inevitably, improvements in flexibility are likely to increase kinking and reduce crush resistance.

The person of ordinary skill in this art would not be motivated to reduce the wall thickness of Darling according to the alleged 'teaching' of Gray.

General Arguments

Dryden discloses a loosely coiled member inside the hose, so that it is not subjected to tensile loads when the hose is stretched linearly (see Abstract). The hose itself is a typical breathing conduit made from polyethylene, having a wall thickness significantly greater than 50 microns. Such tubes are well known in the medical field, and as a matter of absolute necessity, these tubes are sufficiently sturdy such that they do not expand or contract along their length due to fluctuating breath-to-breath internal pressure. This is well known by persons of ordinary skill in the art. Significant volume changes in the conduit are unacceptable because of the disruptive effect on automated ventilation systems, as described in the present specification.

Claim 1, as presented previously (March 9, 2007), requires that the reinforcing member "reinforces said conduit against contraction along the length of said conduit due to fluctuating internal pressure". Given that Dryden and Darling disclose a conduit having a wall thickness much greater than 50 microns, Applicants submit that the hose in Dryden and Darling do **not** contract along its length due to fluctuating internal pressure, as claimed.

As a result, it cannot be said that the inner tube provides any reinforcement against a non-existent effect. Applicant submits that claim 1 is limited by its language to a tube that **would** suffer contraction along its length due to fluctuating internal breath-to-breath pressure **but for** the reinforcing member's reinforcement. The claim language defines a bulk material property of the limb (i.e. that it is sufficiently compliant that it contracts due to fluctuating pressure), and then requires that the tube is reinforced against this defined effect **by** elongate reinforcing member. Applicant submits that the claim does not just recite general reinforcement, but requires reinforcement against a *specifically defined effect*, and further requires that the reinforcement

against this effect come from a separate member. The claim language is limited to a conduit that would contract under specifically defined conditions, but for the elongate reinforcement.

It might be argued that the tube of Dryden and Darling is 'reinforced' in a general manner (albeit to only an insignificant degree). However, if Dryden could be said to be reinforced against this specific effect (i.e. contraction due to internal pressure fluctuation), that 'reinforcement' **must** be coming from the conduit wall itself which sufficiently stiff on its own to resist contraction due to the fluctuating internal pressure. Applicant submits that this is **not** the arrangement claimed in claim 1.

In further support of Applicant's submission that claim 1 *requires* a conduit that **would** suffer contraction along its length due to fluctuating internal breath-to-breath pressure **but for** the reinforcing member's reinforcement, Applicant draws attention to the second paragraph under the Summary of Invention. This paragraph clearly defines the term "very thin walled conduit" (i.e. less then 50 microns as claimed as a conduit where under the intended prevailing conditions the conduit would be subject to excessive axial compression . . ." The "intended prevailing conditions" are described in the summary of the prior art section, as fluctuating breathing pressures (which can lead to substantial internal volume changes).

Claim 1 is quite clearly directed to a limb for a breathing circuit having a very low bulk stiffness such that its volume **would** change under fluctuating internal breath-to-breath pressure, **but for** the claimed reinforcement.

However, even if it is not accepted that the hose of Dryden cannot be said to be reinforced against an effect which it does not suffer, it is submitted that the "loosely coiled" tube being hollow and having outside diameter of 0.115 inches would not prevent contraction as a result of

fluctuating internal pressure. Note that the straight tube shown in Figure 8 is integrally formed with the hose wall, and is therefore not an elongate reinforcing member lying freely within the conduit as claimed.

Interview

Applicant thanks the Examiner for the courtesy extended during the interview on August 8, 2007. During this interview, Applicant's counsel, Linda Palomar, and the Examiner initially discussed the four different hoses sent as samples to the Examiner to ensure that he understood the difference between a "very thin walled conduit" as claimed in the present application, and the typical "thin walled conduit". The Examiner conducted breathing simulations by placing his finger on the end of the conduit and he could see the difference in contraction of the very thin walled conduit versus the thin walled conduit.

Applicant's counsel discussed how in the present invention the reinforcement provides more than a trivial reinforcement (for example, reinforcement according to the claim is not string on a steel bar), and that the axial stiffness of the very thin walled conduit is substantially improved over a very thin walled conduit without the reinforcement.

With regard to Darling, it was discussed that the sheath 24, the conductors 20 and the restraining cords 22 only provide reinforcement against extension. Applicant's counsel discussed that in our opinion, because the thick walled conduit already provides the necessary reinforcement, the sheath 24, the conductors 20 and the restraining cords 22 running therethrough do not provide any appreciable reinforcement. The Examiner maintained that while there is not appreciable reinforcement, the sheath 24, the conductors 20 and the restraining cords 22

nevertheless do provide some reinforcement. The Examiner understood that Applicant is trying to claim more than a trivial reinforcement, but without this specifically recited in the claims coupled with exact support for the language in the specification, the Examiner maintained that the sheath 24, the conductors 20 and the restraining cords 22 of Darling provide the claimed reinforcement. Applicant's counsel submitted that this is not what one of ordinary skill in the art would understand the limitation "reinforcement" to mean from the specification.

With regard to Gray, Applicant's counsel discussed that because of the intended use of the Gray invention, one of ordinary skill in the art would not look to Gray for material choice. The Examiner stated that Gray is applicable and is combinable with Darling or Dryden. The Examiner said that Gray was the secondary reference and he is of the opinion that is correct to combine Gray with Darling or Dryden. The Examiner said that absent something in Darling or Dryden that states that a very thin walled conduit cannot be used, then he is of the opinion that Gray is properly combined with Darling or Dryden.

In addition, the Examiner advised that he has personal knowledge, since he just had venting replaced in his house with a flexible venting, that the vents will elongate when air is being blown therethrough and slacken when air is not being circulated. The Examiner thus claimed that it is his personal knowledge that a very thin walled conduit can compress absent sufficient air pressure.

It was then discussed whether it is proper for Gray to be combined with Darling in view of the fact that one of the intended uses of the Darling conduit is for aircraft. Since the Darling conduit is for use in aircraft, it would not be appropriate to use a very thin walled conduit as a result of the conditions under which the conduit would be placed.

With regard to Dryden, the Examiner maintained his position that the tube 21 provides the claimed reinforcement, despite Applicant's counsel's submission that this is not what one of ordinary skill in the art would understand the limitation "reinforcement" to mean from the specification.

It was also discussed that even if the tube 21 in Dryden provides a "reinforcement", because of its helical nature, the tube 21 would not prevent contraction as a result of internal pressure fluctuations. The Examiner pointed out Fig. 8 of Dryden which shows a straight lumen (but upon further study after the interview, it is clear that 58 is a lumen that is integrally formed with the hose wall; therefore, this cannot be the reinforcement as defined in the claims.).

With regard to the prior amendment, the Examiner stated that because he could not find the word "substantially" in the specification, he cannot allow it in the claims because he contends that it is new matter. Applicant's counsel disagreed that this is new matter because, when reading the specification as a whole, one of ordinary skill in the art would understand that we mean that "substantially" means more than "trivial" and this is therefore supported in the original specification. The Examiner held firm that since he could not find this exact word -- substantially -- in the specification, he would not allow it in the claims.

The Examiner recommended that we amend the independent claim to specify that the reinforcement is "sufficiently stiff to resist buckling under the transiently reduced internal pressures" as provided on page 12, line 6, and provide arguments as to why Darling and Dryden do not meet this limitation. He said that this, along with the other arguments we discussed in the interview, may overcome the prior art, but he would need to do further searching and consideration.

The Examiner also stated that he may be able to allow the "blind termination" of the reinforcement. The Examiner had previously rejected this aspect based upon Dryden. As discussed above, this rejection is incorrect as the tube 21 is not blind terminated.

The Examiner also recommended that dependent claims be added claiming that the reinforcement is made of high density polyethylene and the Young's modulus of the reinforcement. He noted that the "reinforcement" in Darling included the sheath 24, the conductors 20 and the restraining cords 22, and that it may be difficult for him to provide an obviousness argument to replace this structure with high density polyethylene, however, he may be able to find a suitable references showing that it is obvious to substitute high density polyethylene for the polyvinylchloride disclosed in Dryden. The Examiner did state that he thought he would not be able to find a reference to render obvious the Young's modulus provided in the specification.

A Petition for a Two-Month Extension of Time is concurrently submitted herewith to extend the date for response up to and including September 10, 2007 (September 9, 2007 having fallen on a Sunday).

In view of the above Remarks, Applicant respectfully submits that the claims of the application are allowable over the rejections of the Examiner. Should the Examiner have any questions regarding this Amendment, the Examiner is invited to contact one of the undersigned attorneys at (312) 704-1890.

Respectfully submitted,

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By: _____

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